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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/553,941

03/20/2007

Patrick Leahy

KEL01 P-145

6131

28101

7590

09/23/2010

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EXAMINER

COTRONEO, STEVEN J

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

09/23/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/553,941	Applicant(s) LEAHY, PATRICK	
	Examiner STEVEN J. COTRONEO	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

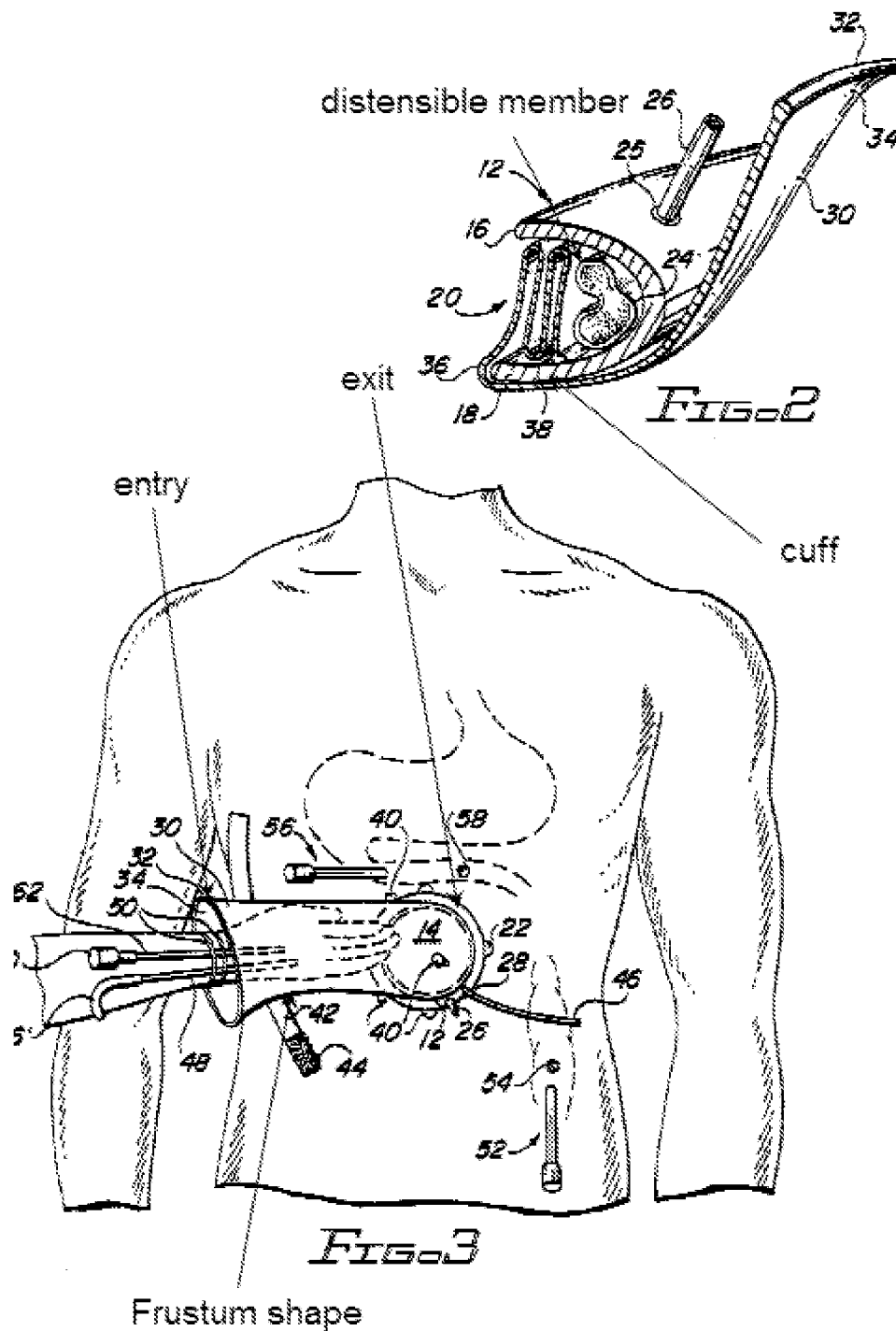
Claims 1, 2, 5-13, 15 and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Leyva (US 5,522,791).

Leyva discloses a surgical device (see figures 2 and 3 below) for use in minimally invasive surgery, the device comprising a sleeve (fig 3, 30) having an exit aperture (fig 3, 14) and an entry aperture (fig 3, 34), the sleeve being shaped and dimensioned to permit the passage of a hand therethrough (fig 3); and a distensible member (fig 2) secured to or formed integrally about the sleeve adjacent the exit aperture. The distensible member annularly located circumferentially at the exit aperture on the exterior of the sleeve (fig 2). The sleeve has a frustum shape with the larger cross section at the entry aperture (fig 3, top is wider). The sleeve is flexible and fluid impermeable (col. 4, ll. 13-16, "latex rubber, plastic or vinyl"). The entry aperture has a reinforcing member (fig 3, 32 and col. 4, ll. 15-20, "gripping loop... resilient flexible material"). A sealing means including a one way valve (fig 3, 40) is provided. A cuff is located around the exit aperture (fig 2, 18).

Leyva discloses the method of passing a hand through the sleeve (fig 3), inserting the distensible member into the surgically cavity and distending the member

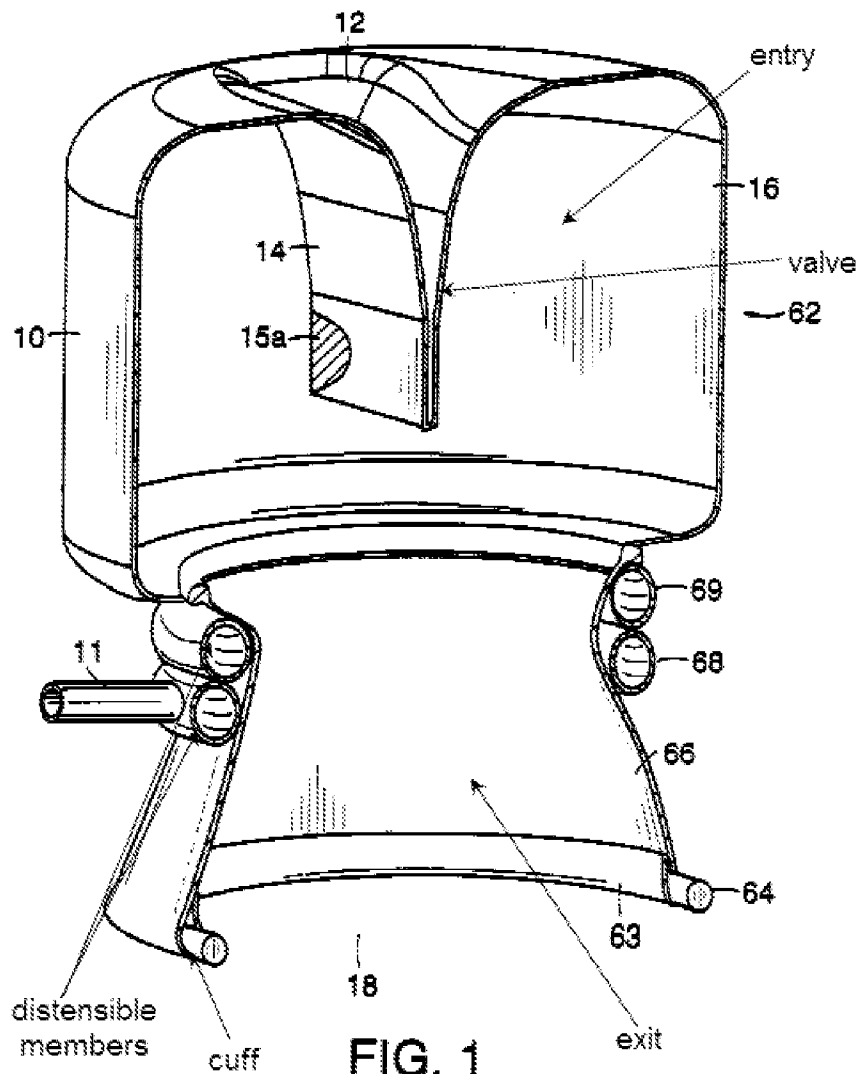
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(col. 6, ll. 1-17). The distensible member is sufficiently distensible to distend the cavity to allow hand assisted surgery to be performed (see fig 3 below. The device is used for hand assisted surgery).



Claims 1-13 and 15-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Beane et al. (US 6,142,936).

Beane et al. discloses a surgical device (see figure 1 below) for use in minimally invasive surgery, the device comprising a sleeve (fig 1) having an exit aperture (fig 1, 18) and an entry aperture (fig 1, 12), the sleeve being shaped and dimensioned to permit the passage of a hand therethrough (fig 11); and a distensible member (fig 1, 68 and 69) secured to or formed integrally about the sleeve adjacent the exit aperture. The distensible member annularly located circumferentially at the exit aperture on the exterior of the sleeve in a plurality of sections (fig 1). The sleeve has a frustum shape with the larger cross section at the entry aperture (fig 1, 10 is wider than 66). The sleeve is flexible and fluid impermeable (col. 13, ll. 18-22, "rubber, plastic"). The sleeve can be transparent (col. 13, ll. 6, "the skirt pocket transparent"). The entry aperture has a reinforcing member (fig 1, 10). A sealing means including a one way valve (fig 1, 14) is provided. A cuff is located around the exit aperture (fig 1, 63). The sleeve has a passage along its length (fig 13, 142). A cover is releasable secured to the entry aperture (fig 7B). **The distensible member is sufficiently distensible to distend the cavity to allow hand assisted surgery to be performed (see figure 10. The device is used for hand assisted surgery).**



Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Leyva (US 5,522,791) in view of Leahy et al. (US 5,640,977).

Leyva discloses the claimed invention except for the sleeve being provided with lubricant.

Leahy et al. discloses a surgical sleeve provided with lubricant (col. 4, ll. 46) to reduce the friction and ease movement of the hand (col. 4, ll. 45-47).

It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the device of Leyva to include the sleeve being provided with lubricant in view of Leahy et al. in order to reduce the friction and ease movement of the hand.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beane et al. (US 6,142,936) in view of Leahy et al. (US 5,640,977).

Beane et al. discloses the claimed invention except for the sleeve being provided with lubricant.

Leahy et al. discloses a surgical sleeve provided with lubricant (col. 4, ll. 46) to reduce the friction and ease movement of the hand (col. 4, ll. 45-47).

It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the device of Beane et al. to include the sleeve being provided with lubricant in view of Leahy et al. in order to reduce the friction and ease movement of the hand.

Response to Arguments

Applicant's arguments, see Remarks, filed 4/29/2010, with respect to USC 112 rejection of claims 2-4 have been fully considered and are persuasive. The USC 112 rejection of claims 2-4 has been withdrawn due to the applicant's amendment.

Applicant's arguments filed 4/29/2010 have been fully considered but they are not persuasive. The applicant argues Leyva and Beane et al. do not have a distensible member that in use allows hand assisted surgery to be performed. The examiner respectfully disagrees. As stated in bold above both the Leyva and Beane et al. devices are used for hand assisted surgery and have a distensible member that can aid in the distending of the cavity to perform the surgery. The applicant argues that the Leyva and Beane et al. devices require the use of insufflation gas to perform the distension. Nothing in the claims requires the device to not use insufflation gas. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., no insufflation gas) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STEVEN J. COTRONEO whose telephone number is (571)270-7388. The examiner can normally be reached on M-F 730-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. C./

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733